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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/377,795	08/20/1999	MICHAEL KARIN	P-UD-3613	8313

23535 7590 03/29/2006
MEDLEN & CARROLL, LLP
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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/377,795

Applicant(s)

KARIN ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

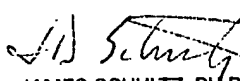
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 13-15.
Claim(s) objected to: _____.
Claim(s) rejected: 11 and 30-34.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


JAMES SCHULTZ, PH.D. TV
PRIMARY EXAMINER March 20, 2006

Continuation of 3. NOTE: The subject matter of the new claims would require a new search and consideration of prior art because these claims are directed to embodiments that have not previously been specifically searched and considered.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the specification provides an embodiment meeting the limitations of claims 11 and 31-34. Arguments with regard to claims 35-40 will not be addressed because these claims have not been entered. The examiner agrees that the specification provides this embodiment but applicant has not demonstrated how the disclosure of this single embodiment provides a representative sample of the full genus of sequences encompassed by the claims. The examiner also recognizes that polypeptides sharing 378 amino acids with SEQ ID NO: 2 would have 90% amino acid identity. No attempt has been made to limit claims to conservative amino acid changes; discussion of conservative amino acids was a response to applicant's arguments that knowledge of conservative amino acid changes in the art provides a description of the claimed genus of sequences.

Applicant additionally argues that the skilled artisan would recognize applicants had possession of the claimed sequences when combining what is known in the art with the correlation between structure and function provided in the specification. Applicant cites as an example the teaching the C and N terminal deletions do not affect the ability of IKK-gamma to bind IKK-alpha and -beta. This argument is not persuasive because the biological activities of IKK-gamma encompassed by the claims are not limited to binding activity. Description of a protein sequence that retains binding activity does not lead the skilled artisan to sequences that encode a protein 90% identical to SEQ ID NO: 2 that has the other biological activities encompassed by the claims.

Applicant asserts that the teachings of example 9 of the written description guidelines should not be limited to hybridization claims. Example 9 of the guidelines is directed to a genus of sequences that must hybridize under stringent conditions to a disclosed SEQ ID NO and encode a protein with a single defined function. The analysis states that this example meets the written description requirement because the skilled artisan would not expect substantial variation among such sequences because stringent hybridization conditions would yield structurally similar DNAs. In this example the isolation of structurally similar DNAs is expected to produce a protein of similar function and this example thus provides a clear structure-function correlation. Such an expectation of structurally similar DNAs does not exist with the instant application, which discloses a protein having numerous functions and claims a genus of sequences that produce structurally divergent proteins having one or more functions. The claims of the instant application are directed to structurally divergent DNAs that produce numerous proteins having multiple functions. The instant application does not provide a clear structure-function correlation.

Applicant requests that the examiner describe the merits of the '961 patent that have entitled Tarczynski et al. to a greater claim breadth than that of the instant application. Applicant's attention is directed to MPEP 1701, which precludes PTO personnel from commenting on the patentability of claims of an issued patent.

Applicant requests that the examiner suggest claim amendments that would overcome the written description rejection. This rejection might be overcome by removing the phrase "at least 90% sequence identity with" from claim 11. However, such an amendment may result in this claim having a scope identical to that of claim 13.

Applicant's representative is put on notice that the statement that "...the Examiner's continued rejection of claim 30 demonstrates a lack of understanding of the law, as well as a failure to properly analyze the amended claim...", runs afoul of the requirement of 37 CFR 1.3 that attorneys and agents conduct their business with the PTO with decorum and courtesy.

Applicant traverses the 102 rejection of claim 30 by stating that Hillier does not teach or suggest a nucleotide sequence complementary to nucleotides 149-1405 of SEQ ID NO: 1 and further argues that Hillier fails to disclose approximately 1.3 kb of the claimed antisense. Applicant appears to be interpreting claim 30 more narrowly than it is written. Because claim 30 recites an antisense complementary to "a" nucleotide sequence, it is not limited to polynucleotides complementary to the entirety of nucleotides 149-1408 of SEQ ID NO: 1. The scope of this claim includes polynucleotides having as few as two nucleotides complementary to the recited nucleotide range. Thus, the sequence disclosed by Hillier that is complementary to nucleotides 1406-1408 meets the limitations of claim 30 as amended.